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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1618]

"Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis" dated August 2001. The guidance document provides recommendations to blood establishments that wish to distribute blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor's disease on the container label, or collect blood more frequently from such individuals than every 8 weeks without a physical examination and certification of the donor's health by a physician on the day of donation. This guidance document identifies conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, and provides guidance on what to submit when requesting these variances. These recommendations apply to all blood establishments, whether or not they hold a U.S. license for the manufacture of blood and blood components. The guidance document announced in this notice finalizes the draft guidance document entitled "Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis" dated December 2000.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics

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Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis" dated August 2001. This guidance document identifies conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, under the provisions of 21 CFR 640.120 and provides guidance on what to submit when requesting these variances.

On April 29, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (ACBSA) recommended that the Department of Health and Human Services (DHHS) "create policies that eliminate incentives to seek [blood] donation for purposes of phlebotomy" from patients with diagnosed hemochromatosis who require phlebotomy as therapy for their disease. Further, as undue incentives to donate blood for transfusion (rather than being therapeutically phlebotomized) are removed, DHHS "should create policies that eliminate barriers to using this resource" to augment the country's blood supply (Ref. 1).

On August 10, 1999, the Commissioner of Food and Drugs made a commitment to consider case-by-case exemptions to existing blood labeling and donor suitability regulations for blood establishments that can verify that therapeutic phlebotomy for hemachromatosis is performed at no expense to the patient (Ref. 2). FDA additionally committed itself to work with the Health Care Financing Administration in ensuring that the financial incentives for persons with hereditary hemochromatosis (HH) to donate blood for transfusion are removed. This issue was further discussed at the FDA Blood Products Advisory Committee meeting on September 16, 1999 (Ref. 3). For the foreseeable future, if blood establishments wish to distribute blood collected from donors with HH without disease labeling, they would be responsible for removing financial incentives for these donors. Each blood center should evaluate the advantages of entering these donors into their donor pool.

The guidance document announced in this notice finalizes the draft guidance document entitled "Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis" dated December 2000. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on blood collection from individuals with hereditary hemochromatosis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Nightingale, S. D., Summary of Advisory Committee Meeting of April 29 and 30, 1999, May 13, 1999 (http://www.hhs.gov/bloodsafety).

2. Henney, J. E., Memorandum Blood Donations by Individuals with Hemochromatosis, August 1999.

3. Blood Products Advisory Committee, 64th Meeting, September 16, 1999 (http://www.fda.gov/ohrms/dockets/ac/acmenu.htm).

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 8/13/01
August 13, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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